The terais of the Kelkar Committee has been extended to examine and consider various recommendations received by it.

Release of antf-Ashthama Drugs

1066. SHRI CHANDRIKA PRASAD TRIPATHI; Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Unstarred Question No. 1679 given in Rajya Sabha on llth May, 1988 and state:

(a) whether it is a fact that Vento lin CR is a sustained release prepara tion oased on Salbutamol;

(b) whether if is a fact that the same has been allowed for marketing in the country in 4 mg and 8 ing tablets;

(c) whether dissolution study, blood level studies and other criteria evalua ting invivo effects of the drugs was done if so what are the details of reports tne preparation has been allow- human consumption without the hission of Government, the action en;

(f) if not; and

(g) what were the tests conducted alongwith the report of each?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH ANp FAMILY WELFARE (KUMARI SAROJ KHAPARDE). (a) to (g) Although control release preparations of old drugs, would fall under the definition of 'now' drug as per the "Guidelines on Introduction of New Drugs", the State Drugs Controllers, in the absence of . guidelines not under statute yet, may have been from time to time in consultation with their experts granting permission of control release preparations of old drugs including the one under Question.

The Central Government has no in- formation as to whether permission of such control release preparatinos were granted on the basis of blood level studies, since such permissions were granted by the State Drugs Control Authorities.

Clearnace of combination Diclofenac Sodium and Paracetamol for marketing

1067. SHRI CHANDRIKA PRASAD TRIPATHI: Will the Minister of" HEALTH AND FAMILY WELFARE be pleased to state;

(a) whether it is a fact that combi nation of Diclomenac Solium with Para cetamol has been allowed for market ing in the country by State Drug Au thorities, Gujarat

(b) if so, what is the rational thereof and whether the Ministry of Health and Family Welfare has studied and approved the rationality;

(c) whether any trials was conducted in the country for this combination;

(d) if so, the details thereof;

(e) whether the combination is being marketed in any other country of the would;

(f)l the names of those countries;

(g) whether any expert were consulted before granting permission-.

(h) if so, the names of the experts alongwith the details of findings of each;

(i) whether Ministry of Health and Family Welfare has studied the reports, date and are satisfied therewith; and

(j) if not, by when the Ministry proposes to study the rationality and other factors- involved in the matter?

THE MINISTER OF STATE IN THE - MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE). (a) to (j) Although fixed dose combination of drugs like Diclofenac Sodium and paracetamol would fall under the purview of the